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Letters to the Editor

Dear Editor

Informed consent for bronchoscopy

Bronchoscopy and pre-medication are rarely associated with undesidered side-effects, but they are not free of them. For this reason, the process of informed consent is an ethical, legal and medical necessity for endoscopists before performing endoscopic examinations, and the patients are commonly requested to sign a written consent form before undergoing bronchoscopy. Unfortunately, such forms are not standardized in Italy, and every endoscopy centre utilizes its own form that is usually drawn up by physicians working in the centre. These forms are often inadequate, as they do not include several pieces of key information and do not fulfil many essential principles of good clinical practice.

We report here a consent form we recently observed (Fig. 1). Neither explanations concerning the mode of endoscopic procedure, nor information about risks and complications are included. In place of them, the form reports the following words: '. . . informed me of the nature and purpose of the procedure, as well as the anticipated benefits, possible complications from known and unknown causes, foreseeable and unforeseeable risks, . . .'

What are the complications from unknown causes and the unforeseeable risks of bronchoscopy? How can physicians disclose them to patients?

This is an example of the confusion reigning among endoscopists. Many physicians see consent forms primarily as protecting facilities from liability, but a signed consent form, like the above-mentioned one, is conclusive merely as to the issue of consent and not the adequacy of disclosure. In fact, there is no rational relationship between the fact proved (that the consent form was signed) and the fact presumed (that the patient was adequately informed).

It is known that the written consent form mainly serves as a defence against a charge of unauthorized treatment (i.e. battery) and not to a claim of inadequate disclosure (i.e. negligence) (1). Notwithstanding this, correct consent forms are useful and important, as they can also be seen as part of the process of physicians educating patients about the proposed treatment (2). Obviously, information is propaedeutical to understanding, and understanding is propaedeutical to consent.

INFORMED CONSENT FOR BRONCHOSCOPY

Patient's name.....

1) I empower the physicians working in this department to carry-out all necessary diagnostic and therapeutic procedures.

2) Doctor..... has exhaustively informed me of the nature and purpose of the procedure, as well as the anticipated benefits, possible complications from known and unknown causes, foreseeable and unforeseeable risks, and possible alternatives to the procedure. All my questions have been answered exhaustively and satisfactorily.

3) I am aware that the results of the diagnostic and/or therapeutic procedure are not warranted.

4) After reading the present form, I consciously consent to undergo bronchoscopy.

Signature.....

Fig. 1 Consent form for bronchoscopy used in an Italian endoscopy centre.

Components of informed consent require that: (1) consent be voluntary; (2) the patient be sufficiently mentally capable to engage in rational decision-making; and (3) adequate information be conveyed. Controversies reflected in both medical and legal literature concern the definition of 'adequate information'. It is widely accepted that an informed consent form for endoscopic investigations must inform patients of the nature, purpose, indications, controindications, mode of procedure, risks and benefits of the investigation, as well as any alternative forms of diagnosis and/or treatment (3). Only after reading and understanding such information, can the patient consciously consent to undergo endoscopic investigation.

We believe that the confusion concerning such an issue must be resolved. Chest physicians' associations

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should state appropriate guidelines for disclosing detailed information.

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Dear Editor

New human light on bovine TB in cattle and wildlife?

Progress towards the eradication of tuberculosis in man and livestock is being hampered by problems of diagnosis and misunderstandings as to aetiology and pathogenesis. Consequently, a comparison between species may be fruitful.

The difficulty of early and reliable diagnosis is a hindrance as regards both man and cattle (1,2). Skin tests for both species may mis-identify both false positive cases which do not have TB, and false negative cases which do have TB. The critical importance of more sensitive, faster blood or DNA tests would hence lie in picking up 'missed' TB carriers more rapidly, allowing for earlier chemotherapy and regression to a non-infectious state in man, for removal from the herd in cattle, thus minimizing onward transmission to new hosts. This is of particular importance in cattle TB eradication schemes, since the skin test is, in practice, only 80% sensitive. Elderly, much tested, dairy cows may be desensitized, particularly during pregnancy which alters the immune response. Three TB carriers missed in this way caused 18 herd breakdowns (3).

During the late stages of cattle TB eradication, the number of false positive 'reactors' may reach 80% of cases so that actual TB carriers are much harder to pick up. Two in three 'TB Reactor Herds' in England and Ulster currently turn out not to have TB on culturing (4). This has two major implications for the TB eradication scheme. Farms are subject to 4 months minimum herd movement restriction needlessly, and this costly annoyance could be avoided by immediately repeatable blood tests such as gamma interferon. Perhaps even more importantly, this may be the explanation for the pivotal misunderstanding in the Ministry of Agriculture's TB scheme. It is claimed that only cattle with visibly lesioned (VL) lungs are infectious so that cattle are of little significance in passing TB to either other cattle or badgers, and hence badger culling is justified (5). However, there seems to be confusion between the two in three non-visibly lesioned (NVL) herds which produce no TB cattle nor TB badgers, and a small but highly significant minority of early TB cases which have 'overt' lesions but are nevertheless infectious. This would explain why NVL cases may simply be preclinical cases which in 70–80% of cattle have been exposed to *Mycobacterium bovis*. Such cases would then be the 'undisclosed' source of clusters of contiguous herd breakdowns (6–9). Underestimation of these factors and longer test intervals has led to slippage in the removal of VL/NVL cattle and further evidence that the problem has been mis-tested cattle all along, with a spillover of TB to badgers (6,10).

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